Take5Care+: A self-management educational intervention to support haematology patients' journey following a neoplastic diagnosis

Participant Information Sheet

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You are being invited to take part in a research study by The Open University (OU) and Northampton General Hospital (NGH). Before you decide whether or not to participate, it is important to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Take your time to decide whether or not you wish to take part.

What is the purpose of the study?

Most people want to stay in good health for longer, and research tells us there are lots of easy habits that can help you stay strong, sharp, independent, and feel good. Take Five to Age Well (Take Five) was designed to empower people to achieve effective, long-term self-management of their health and staying healthy by introducing 'bite- size', everyday actions that are available to all. In 2023 and 2025 over 5000 individuals committed to a daily healthy habit for 30 days as part of Take Five.

Research has found that receiving a medical diagnosis can boost motivation for making a healthy behaviour change. This study explores the use of Take5Care+, an intervention based on the Take Five model but co-designed with patients who have similar diagnoses to you. We want to find out if it can empower you to adopt healthy changes during 30 days that will genuinely impact your health and well-being. There are 5 areas where you can choose new habits as part of this intervention:

- **Eat**: healthy eating can boost your health
- **Drink**: staying hydrated as well as the quality of what you drink are key to healthy ageing
- **Move**: Exercise boosts body and mind
- **Engage and connect**: making and maintaining social connections for your health
- **Think**: use your brain to stay sharp

We will invite 20 individuals with a recent diagnosis to take part in this intervention to explore the benefit of committing to a healthy behaviour change. We will also invite clinicians to take part in focus groups to explore the feasibility of using this intervention in the hospital. Due to your recent oncological diagnosis you may benefit from taking part in the study and follow one of the above healthy habits.

Do you have to take part?

No. It is entirely up to you to decide whether to take part. If you do decide to take part we will share your contact details with the research team and ask you to come to NGH to sign a consent form. You will still be free to withdraw at any time without giving a reason. Should you have questions at any stage, don't hesitate to contact a member of the research team.

What will happen to you if you take part?

If you decide to take part you will choose at least one manageable daily habit from our list and commit to it for 30 days.

You will first be asked to visit NGH to meet the research nurse. During this visit you will give your consent to participate in the study, complete a survey about your current healthy habits and choose the habit you want to commit to. You will start your healthy habit on a date of your choosing, supported by the Research Associate via regular emails. At the end of the 30 days, you will be contacted by the Research Associate to fill out a second survey remotely. Three months after you will be contacted by the Research Associate to complete the third and final survey remotely. Each of the three surveys will take approximately 15 minutes to complete.

After the second survey you may also be invited to take part in a 15-20 interview about your experience of taking part in the intervention. You do not have to take part in the interview if invited and it will not affect your participation in the current intervention.

How will we use information about you?

We will need to use information from you and your medical records for this research project. This information will include your name and contact details. The research team will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will also collect information from you via surveys and interviews throughout the study. This will include information about your health and health-related attitudes and behaviours. Only the people in the research team will have access to this data. However, if you make a disclosure of harm during the study, it is our duty to report it to the clinical care team.

The Open University is the sponsor of this research and is responsible for looking after your information. We will not share your information related to this research project with any other organisations. We will keep all information about you safe and secure by storing it on a secure site that is only accessible to the research team.

International transfers

Your data will not be shared outside the UK.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way so that no-one can work out that you took part in the study. We will keep your study data for a maximum of ten years. The study data will then be fully anonymized and securely archived or destroyed.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of the data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Are there any risks or benefits to taking part?

There is no direct risk to taking part. The questionnaires and interviews do not include questions that are likely to be distressing or sensitive. All the available actions have been screened by clinicians to ensure that they are manageable. If you take part in the study and do feel that one of the actions may be contributing to worse health, it is important that you stop at once and notify the research team. In the unlikely event that you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action for compensation against the OU and/or NGH.

By taking part in the study, you will be contributing to research which may benefit others who have recently received a diagnosis. Participation in this study may also lead to positive health benefits if you stay committed to the chosen action.

As part of our risk assessment we only invite participants where the exclusion criteria does not apply. Your consultant will already have screened this list prior to inviting you but please read the list carefully and let us know if you think that any of the exclusion criteria applies to you.

You will not get paid for participation in this study but you will be reimbursed for travel expenses due to the first visit to NGH.

This research project has been given a favourable opinion by the Health Research Authority and Research Ethics Committee – HRA REC reference number: 26/WM/0085

What if you have a complaint?

If you have a concern about any aspect of this study, please contact the NGH Patient Advice Liaison Service: [insert NGH PALS contact details after approval].

What will happen to the results of the study?

We will share the findings of this research as widely as possible in academic and non-academic formats (including on social media, in podcasts, conferences, and the wider mainstream media). We may use quotes from our interviews with you but your data will not be identifiable in any study outputs.

Who is organising and funding the research?

The research is being conducted by the Open University but the study site is NGH. The research is funded by the Northampton Health Charity with funds initially offered to the Charity by a private donor who received a similar diagnosis to yours. If you are interested in participating in this research study, please let the research nurse know when they can contact you. Together you will decide on a date to visit the NGH where you will give your consent to participate in the research and fill out the first survey. Organising a visit with the research nurse does not place you under any obligation to participate. You are free to change your mind at any stage.

Where can you find out more about how your information is being used?

You can find out more about how we use your information by asking one of the research team or sending an email to the Data Protection Officer: data-protection@open.ac.uk

If you are concerned about the way we have processed your personal information, you can contact the Information Commissioner's Office (ICO). Please visit the ICO's website for further details: https://ico.org.uk/

Participant exclusion criteria:

As part of our risk assessment we have decided to exclude any participants who are/have:

- Receiving intensive chemotherapy, radiotherapy, immunotherapy, IV combination regimens, cellular therapy, or treatments requiring inpatient initiation.
- Received or expected to require regular blood product transfusions
- Life expectancy under 12 months.
- Acutely terminal illness.
- Not able to walk much or look after themselves
- Cognitive impairment that would prevent the patient from giving informed consent, or reliably completing the daily action and follow-up assessments
- Pregnant or lactating.
- Already participating in a behavioural research intervention or a clinical medical product trial.
- Aged below 18 years.
- Unstable, uncontrolled, or severe comorbidities including:
    - Uncontrolled heart failure, unstable angina, or MI in the last 3 months.
    - Stroke/TIA in the last 3 months.
    - Severe/unstable COPD or asthma with recent exacerbations.
    - Poorly controlled diabetes
    - Severe psychiatric illness interfering with participation.
- Concurrent active malignancy requiring systemic therapy.